UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 0 7 2017

[redacted]

[redacted]

Re: PMN **P-16-0417**

Dear [redacted]:

This letter concerns the above-referenced premanufacture notice (PMN) which you submitted pursuant to section 5(a) of the Toxic Substances Control Act (TSCA) and 40 CFR Part 720. The PMN described the chemical substance as [redacted].

The Environmental Protection Agency (EPA) has made an interim determination under sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA that the manufacturing, processing, distribution in commerce, use, or disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment under the conditions of use and foreseeable conditions of use. This letter provides you with the basis of EPA's interim determination of potential unreasonable risk and describes your options in light of this interim determination.

This interim determination is based on physical chemical properties of the chemical as well as estimates of potential hazard based on Structure Activity Relationship (SAR) analysis derived from test data on structurally similar diisocyana tes (See https://www.epa.gov/tsca-screening-tools). Based on this SAR analysis and the SDS data, EPA has concern that the PMN substance may cause irritation and sensitivity to all tissues in workers and the general population exposed to the PMN substance by the inhalation and dermal route. However, a change in the relative amounts of the starting materials or manufacturing processes could result in higher residual diisocyanate starting materials or isocyanate on the polymer that would result in higher concerns for human health hazard. In the absence of data specific to your PMN substance, EPA uses estimates of predicted toxicity and exposures.

Given EPA's interim determination, EPA will regulate this substance pending the development of sufficient information to reduce the uncertainties in the unreasonable risk determination. Your company has several options available.

Option 1. Your first option is to enter into an expedited section 5(c) Consent Order. The

Consent Order would permit limited manufacture, processing, distribution in commerce, use, and disposal of the substance, pending the development by your company and subsequent review by EPA of information addressing the potential risks. Signing the Order would finalize EPA's determination under section 5(a)(3) of TSCA but would not constitute an admission by your company as to the facts or conclusions underlying the Agency's determination in this proceeding.

A generic section 5(e) Order may be found on the Internet at: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-program-boilerplates. The generic Order provides an example of the standard language EPA uses in section 5(e) Orders of this type. Please note, however, that the generic Order was developed for various possible cases and therefore many of its provisions may not apply to this PMN substance.

For this PMN substance, the Consent Order would likely require your company to comply with the following provisions (Note: the following list is only a tentative list (i.e., not final list) of possible provisions):

(1) conduct and submit certain testing to EPA. This testing would be required to be submitted to EPA for review before a certain production volume or period of time (to be specified in the Consent Order) is reached based on EPA's assessment of potential exposures and risks associated with the intended, known or reasonably foreseen uses of the PMN. The required testing may include the following tests:

- Skin Senstitization Study (OPPTS 870.2600); and
- 90-Inhalation Toxicity with a 60 day holding period (OPPTS 870.3465).

(2) manufacture (which includes import) the substance with an isocyanate residual of less than 0.1 percent;

(3) require workers exposed dermally to wear personal protective equipment;

(4) require engineering controls and/or require workers exposed via inhalation to wear NIOSH-approved respirators (to be specified in the Order);

(5) comply with the labeling, Safety Data Sheet (SDS), and worker training provisions in the Hazard Communication Program section of the Order;

(6) distribute the PMN substance only to a person who agrees to follow the same restrictions applicable to your company (except the testing requirements) and to not further distribute the PMN substance until it has been completely reacted or cured;

(7) limit use to industrial use as [redacted] (i.e., no commercial or consumer use); and

(8) maintain relevant records.

The majority of TSCA section 5(e) Consent Orders are now developed via an expedited concurrence procedure. Under this procedure, an Order with the provisions listed above, and/or other provisions deemed to be needed by EPA, will be developed directly from the standard Order language, signed by the Director of the Chemical Control Division, and sent to you for signature. This would allow you to commence manufacture (which includes import) immediately after EPA's receipt of the Order with your signature, instead of waiting for further internal Agency review and concurrence, provided that the statutory 90-day review period has ended. To take advantage of the expedited concurrence procedure, you must agree to accept the Order signed by EPA without modification.

To begin work developing the Consent Order, EPA will require from you a written suspension of the PMN review period for at least 60 days to permit development of the Order. This is the minimum period of time required to develop and obtain final signatures for a section 5(e) Order. Additional suspensions to provide more time may be required if, during the development process, your company presents new facts which necessitate modifications to the Order language. If, however, any suspension time remains in effect when the Order is signed, EPA will revoke the remainder of the suspension period to make the Order effective immediately. Suspensions of the PMN review period are authorized by 40 CFR 720.75(b).

After your company commences manufacture of the PMN substance and submits a notice of commencement (NOC) of manufacture within 30 days as required by 40 CFR 720.102, EPA will add the substance to the TSCA Chemical Substances Inventory maintained pursuant to section 8(b) of TSCA. The substance will no longer be a "new chemical substance" as defined by section 3(a) of TSCA. Consequently, any other company may manufacture the substance without being required to submit a PMN or comply with any other restrictions under section 5 of TSCA, unless EPA promulgates a "significant new use rule" (SNUR) pursuant to section 5(a)(2) of TSCA. Therefore, if a Consent Order is developed for this PMN substance, EPA intends to develop a SNUR concurrently with the Consent Order. The SNUR will contain essentially the same provisions as the Consent Order and will extend those provisions to all other companies which manufacture or process the PMN substance after the effective date of the rule. According to section 5(a)(1)(A)(ii) of TSCA, any company wishing to engage in an activity designated by the SNUR as a "significant new use" must submit a significant new use notice (SNUN) to EPA at least 90 days before doing so. Section 5(a)(1)(B)(ii) of TSCA prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

Option 2. The second option is that you may elect to discuss modifications to the standard language of the Order. Please note, however, that modifications to standard Order language could significantly lengthen the amount of time required to develop both your Order and the corresponding SNUR. Any deviation from the standard language will necessitate more extensive Agency review, making the expedited procedures impossible. If you wish to pursue

this option, you should submit to EPA a written suspension of at least 90 days. Additional suspensions may be required depending upon the complexity of the changes being sought and the amount of time your company spends reviewing the document.

Option 3. A third option is, before commencing any manufacture (which includes import) of the PMN substance, to submit to EPA other information on the potential effects, releases, or exposures of the PMN substance that you believe may refute EPA's interim determination of potential unreasonable risk under section 5(a)(3) of TSCA as described above. Upon Agency review, such information may influence EPA's determination of whether and how to regulate this chemical substance and might substitute for some or all of the testing described in Option 1. A suspension of the review period for a time adequate to allow for EPA to review the submitted information may also be necessary for Option 3.

The Agency strongly encourages you to consider exploration of methods of source reduction, pollution prevention, or recycling. The Pollution Prevention Act of 1990 and EPA's Pollution Prevention Strategy (56 Federal Register 7849, February 26, 1991), rank preferences in methods of controlling chemical risks as follows: source reduction first, recycling second, treatment third, and disposal last. The rationale for this ranking order is that, environmentally and economically, it is usually better to avoid creation of a pollutant than to subsequently control exposures and releases by shifting a pollutant among environmental media (e.g., water, air, land). For additional information on pollution prevention, you may view EPA's Pollution Prevention Home-Page on the Internet at https://www.epa.gov/p2.

Option 4. Another option is to withdraw your PMN. Such a withdrawal will not prejudice any right to resubmit in the future a PMN or exemption notice for the same substance to EPA under section 5(a) or 5(h) of TSCA. A written notice of withdrawal must be sent to EPA in accordance with 40 CFR 720.75(e).

Response to EPA in 30 days. Within 30 days of your receipt of this letter, please complete and return to EPA's Program Manager the enclosed "Selection of Regulatory Options" form, which will notify EPA of your company's decision as to which option it wishes to pursue. If you decide to pursue certain options, you should also include a request to suspend the PMN review period on the enclosed form, as indicated there.

Failure to respond. If you do not complete and return, within 30 days, the enclosed form indicating your decision and providing an adequate suspension of the review period to pursue one of the above options, EPA will assume that you do not wish to pursue a negotiated approach to the resolution of this PMN review. Under this scenario, EPA may unilaterally issue an Order under section 5(e) of TSCA that may completely prohibit the manufacture, processing, distribution in commerce, use, or disposal of the PMN substance pending the development of information sufficient to permit a reasoned evaluation of the effects of the substance. Consequently, EPA would issue a notice under section 5(c) of TSCA extending the PMN review period by an additional 90 days (i.e., to a total of 180 days) to permit development of the Order under section 5(e). In addition, you may be contacted by a representative of the Information

Management Division (IMD), Office of Pollution Prevention and Toxics (OPPT), and be required to substantiate certain Confidential Business Information (CBI) claims in your PMN as a condition of maintaining the information as CBI.

Under section 5(e), EPA would issue the Order no later than day-135 of the extended PMN review period and, on or before the day the Order is issued, notify you in writing of the basis of the determination underlying the Order. The Order would become effective upon the expiration of the review period.

Regardless of which option you pursue, you are required by section 5(h)(3) of TSCA and 40 CFR 720.36 to notify persons engaged in research and development activities (R&D) of the potential risk to health described in this letter.

EPA contact. If you have any questions or comments, please contact Geraldine Hilton, the Program Manager for this PMN, at (202) 564-8986.

Sincerely,

Greg Schweer, Chief
New Chemicals Management Branch
Chemical Control Division (7405 M)

Enclosure

SELECTION OF REGULATORY [redacted]

FOR PMN # P-16-0[redacted]

I have reviewed the Agency's letter dated February 15, 2017, which outlines the regulatory options for the above-referenced PMN, and I select the following option:

[ ] Option 1 - Expedited, non-negotiated, section 5(e) Consent Order
(60-day suspension recommended)

[ ] Option 2 - Negotiated section 5(e) Consent Order
(90-day suspension recommended)

[ ] Option 3 - Upfront submission of data before EPA makes final determination under section 5(a)(3) of TSCA (suspension as appropriate)

[ ] Option 4 - Withdrawal of PMN per 40 CFR 720.75(e)
(no suspension necessary)

To provide time for implementation of the selected option, I request, pursuant to 40 CFR 720.75(b), a suspension of the PMN review period until the following date: _____.

_____ _____

Date Signature

Name:

Title:

Company: